

| Market Applicability/Effective Date | | | | | | | | | | | | | | | |
|-------------------------------------|----|----------|--------|--------|----|-----|----|----|----|----|----|----|-----|-----|----|
| Market | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
| Applicable | X | X | N/A | N/A | X | N/A | X | X | X | X | X | X | N/A | N/A | X |

*FHK- Florida Healthy Kids

Gazyva (obinutuzumab)

DRUG.00062

| Override(s) | Approval Duration |
|---------------------|-------------------|
| Prior Authorization | 1 year |

APPROVAL CRITERIA

- I. Requests for Gazyva (obinutuzumab) may be approved when either of the following criteria are met:
 - A. As first-line treatment of chronic lymphocytic leukemia /small lymphocytic lymphoma without del (17p) mutation, when used in combination with chlorambucil; **OR**
 - B. As a single agent for the treatment of relapsed/refractory chronic lymphocytic leukemia/small lymphocytic lymphoma without del (17p) mutation.

OR

- II. Requests for Gazyva (obinutuzumab) may be approved as a treatment of follicular lymphoma when used as a component of *one* of the following combination chemotherapy regimens (A., B. or C. below) *and* as monotherapy, for up to 24 months or until disease progression, following the listed combination therapy regimens:
 - A. Cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP regimen); **OR**
 - B. Cyclophosphamide, vincristine, and prednisone (CVP regimen); **OR**
 - C. Bendamustine.

Gazyva (obinutuzumab) **may not be approved** for the following:

- I. When the above criteria are not met and for all other indications, including but not limited to diffuse large B-cell lymphoma and mantle-cell lymphoma.

NOTE

Gazyva (obinutuzumab) has black box warnings for hepatitis B reactivation and progressive multifocal leukoencephalopathy (PML). Hepatitis B Virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, can occur with Gazyva. Individuals should be screened for HBV prior to treatment initiation and those with HBV monitored during and after treatment. Therapy should be discontinued in the event of HBV reactivation. PML, including fatal PML, can occur with Gazyva therapy. Individual should be premedicated with a glucocorticoid, acetaminophen and an antihistamine for infusion reaction prophylaxis.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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| Applicable | X | X | N/A | N/A | X | N/A | X | X | X | X | X | X | N/A | N/A | X |

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| State Specific Mandates | | |
|-------------------------|----------------|---|
| State name | Date effective | Mandate details (including specific bill if applicable) |
| N/A | N/A | N/A |

Key References:

Bauer K, Rancea M, Roloff V, et al. Rituximab, ofatumumab and other monoclonal anti-CD20 antibodies for chronic lymphocytic leukaemia. Cochrane Database Syst Rev. 2012;(11):CD008079.

Gazyva [Product Information]. South San Francisco, CA. Genentech, Inc.; February 01, 2016. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125486s013lbl.pdf. Accessed on September 25, 2017.

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- B-Cell Lymphomas (V5.2017). September 28, 2017.
- Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (V1.2018). September 08, 2017.

Obinutuzumab. In: DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated August 15, 2017. Available at: <http://www.micromedexsolutions.com>. Accessed on September 25, 2017

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